REMARKS

Status of the Claims

Claims 36, 38-40, 42-44, 46-48, and 50-54 are pending in this application.

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected.

Although there are no amendments to the claims, a complete listing of the claims is provided for the Examiner's convenience.

Claim Rejections

35 U.S.C. § 112

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, and 35 U.S.C. § 112, second paragraph, as allegedly failing to set forth the subject matter which applicants regard as their invention.

In each case, the Examiner mischaracterizes the passage from page 6, lines 7-13 of the specification to argue that the "perilla oil must be 'aged' or 'stored' prior to obtaining PPAR activity" for use in accordance with the present invention. [OA, pp. 2-3]. Additionally, despite the fact that neither of the working examples indicates that 'aged" or 'stored' perilla oil is necessary for the claimed composition, the Examiner states that "silence of the instant examples about the age of the perilla oil is not a teaching away from use of aged perilla oil" [OA, at p. 3]. The Examiner therefore contends that the claims lack written description and depart from what the applicants regarded as their invention inasmuch as the claims do not require aged or stored perilla oil but "suggest instead that fresh perilla oil treats cellulite" [OA, p. 3]. Applicants respectfully disagree and assert that the Examiner's speculative allegation that the claimed method requires an 'aged' or 'stored' limitation to satisfy the requirements under 35 U.S.C. § 112 is contrary to established case law.

The Examiner misinterprets the following passage from page 6, lines 7-13 of the specification as indicating that perilla oil must be 'aged' or 'stored' prior to obtaining PPAR activity:

> It is surprising and unexpected that perilla oil inhibits upregulation by PPAR agonists, as perilla oil itself contains PPAR agonists such as linolenic acid and linoleic acid. This ***may*** be attributable to perilla oil undergoing oxidation on storage due to the high content of unsaturated fatty acids. The oxidation process ***may*** alter the PPAR stimulation activity of linolenic acid and linoleic acid, causing the acids to bind to and shield the receptors, but not activate them, thereby preventing other agonists from reaching and activating the receptors. [Id. (emphasis added)]

Contrary to the Examiner's statement that the perilla oil "must" be aged or stored, the cited passage merely equivocates that the unexpected inhibitory activity "may" be attributable to oxidation on storage. In other words, the cited passage does not clearly indicate that the perilla oil must be aged or stored to have inhibitory activity. Accordingly, requiring such equivocal language as a claim limitation is contrary to established case law See, Amgen v. Hoeschst Marion Roussel, Inc, 314 F.3d 1313 (Fed. Cir. 2003) (holding improper the importation of a claim limitation based on language in the specification that does not clearly indicate such limitation is the only possible mode of the invention) (distinguishing Gentry Gallery v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998).

Further, although "silence of the instant examples about the age of the perilla oil is not a teaching away from use of aged perilla oil," neither is it a teaching that the age of the perilla oil is of significance. Indeed, the most logical reading of Examples 1 and 2 is that the invention was not intended to be limited to aged or stored perilla oil because perilla oil is shown to completely or significantly prevent PPAR upregulation in the presence of an agonist without any mention that the perilla oil used in those examples was aged or stored or comprised oxidized fatty acids.

The Examiner states that U.S. Patent No. 5,312,834 ("Yeo") "teaches a composition of perilla oil . . . that should have the same activity, but the instant specification teaches that it does not" [OA, p. 3]. Again, the Examiner mischaracterizes the teachings of the instant specification, which states:

> U.S. Patent No. 5,312,834 to Yeo teaches compositions for the treatment of acne. The Yeo

> patent exemplifies topical compositions having both eicosapentaenoic acid and alpha-linolenic acid, preferably in a weight ratio of 1:0.1 to 20, respectively. Although Yeo teaches that perilla oil contains alpha-linolenic acid and fish oil contains eicosapentaenoic acid, Yeo fails to teach or suggest that perilla oil would be effective to treat acne, absent the required ratio of eicosapentaenoic acid to alpha-linolenic acid.

It is not seen how this is a teaching that Yeo's perilla oil has any different properties than the perilla oil useful in treating cellulite according to the present invention. It will be observed that Yeo teaches **oral** rather topical administration of his composition. See Yeo, at Col. 4, lines 49-66 (indicating that the disclosed compositions may be administered in the form of syrups or soft capsules and that a therapeutic effect can be obtained by administering one spoon (15 ml) of the composition every eight hours thrice daily). As such, the discourse regarding whether or not the perilla oil disclosed by Yeo has PPAR activity is irrelevant.

The Examiner also alleges that there "exists another written description issue in that there is no correlation between *in vivo* and *in vitro* results and the instant specification only describes treating cells with the composition, not topical application onto the skin as is instant claimed" [OA, p. 6]. As an initial matter, Applicants fail to see how the issue of a correlation between *in vivo* and *in vitro* results has any bearing on the written description requirement, as opposed to the enablement requirement, of §112, first paragraph. The written description analysis focuses on whether Applicants were in possession of the claimed invention at the time the application was filed. In that regard, the specification unambiguously states on page 5, lines 5-9, that "[w]hen the topical composition has from about 0.01 wt% to about 10 wt% perilla oil in a cream vehicle, it is believed that such a composition should, preferably, be applied . . . one to two times a day for cellulite conditions." It cannot be reasonably argued that Applicants were not in possession of "topical application onto the skin as is instant claimed," as alleged by the Examiner, because the specification established nearly verbatim that Applicants were in possession of this aspect of the invention.

Moreover, as to the correlation between *in vivo* and *in vitro* results, Applicants point out that an enablement rejection raising similar issues has previously been overcome in the case and respectfully direct the Examiner's attention to the response filed May 31, 2007. In that

paper, Applicants provided evidence that PPAR is recognized as playing a central role in cellulite etiology and Applicants further pointed out that the USPTO has issued a patent (U.S. Pat. No. 6,852,343) for a topical oil which reduces PPAR mRNA expression for the treatment of cellulite which itself relies on *in vitro* models of PPAR regulation. Accordingly, Applicants respectfully assert that the *in vitro* examples in the specification reasonably correlate with the claimed utility *in vivo*, and, in any event, the Examiner has provided no evidence to rebut this conclusion. Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. §112.

35 U.S.C. § 103

Claims 36, 38-40, 42-44, 46-48, and 50-54 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 5,945,109 ("Schmidt") in view of U.S. Patent No. 5,312,834 ("Yeo"). The Examiner states that Schmidt discloses a "cosmetic product for topical administration for cellulite" which may comprise "essential oils and plant extracts" including "groundnut oil." The Examiner specifically points to Example 1 of Schmidt which discloses an anti-cellulite cream comprising 10% by weight "Hardened groundnut oil." The Examiner acknowledges that Schmidt does not disclose perilla oil but relies on Yeo as teaching "a composition comprising perilla oil." The Examiner contends that one skilled in the art would have been motivated to include perilla oil, as taught by Yeo, in the anti-cellulite creams of Schmidt because Yeo teaches that perilla oil "has no side effects" whereas groundnut oil is a "known allergen." Applicants traverse this rejection.

This rejection is improper for at least the reason that the Examiner has not offered a sufficient rationale, absent hindsight, as to why one skilled in the art would have been motivated to include perilla oil in Schmidt's anti-cellulite compositions. Yeo relates to an oral composition for treating acne which may comprise perilla oil. Yeo's compositions are for oral delivery whereas the anti-cellulite compositions of Schmidt are topical. Specifically, Yeo teaches that the "composition of the present invention may be administered in the form of syrups or may be concentrated and filled in soft capsules" [col. 4, lines 49-51], and that "a satisfactory therapeutic effect can be obtained by administering one spoon (15 ml) of the composition every eight hours, three times a day" [col. 4, lines 60-66]. Thus, there is no teaching or suggestion in

any of the cited art that perilla oil may be safe or efficacious for topical application against any condition, let alone cellulite.

The Examiner's contention that the limited teachings of the cited references would have provided specific motivation to replace Schmidt's "hardened groundnut oil" with Yeo's perilla oil is baseless. At the most, one would have been motivated to employ a non-allergenic (refined) grade of peanut oil in Schmidt's compositions in view of the allergenic nature of some crude grades of peanut oil.[1]

But, the Examiner has offered no evidence whatsoever that one skilled in the art would have considered perilla oil to be a suitable substitute for "hardened groundnut oil" in topical preparations. The Examiner offers no evidence that they possess similar physical or chemical characteristics that would have led one skilled in the art to consider them to be interchangeable. For example, the Examiner ignores the fact that Example 1 of Schmidt calls for not simply a groundnut oil, but rather a "hardened" groundnut oil. Indeed, the Examiner's reasoning leads to the logical absurdity that it would have been obvious to treat cellulite with any non-allergenic oil. Of course, absent hindsight, there simply would have been no motivation to make the modification suggested by the Examiner. That the rejection is based on hindsight is clear from the observation that had Schmidt recognized that perilla oil could treat cellulite, it would surely had been included and disclosed as a suitable component of his anti-cellulite cream.

As such, an ordinarily skilled artisan reading Schmidt and Yeo would not be motivated to substitute the hardened groundnut oil of Schmidt with the perilla oil of Yeo. Rather, Applicants respectfully submit that the Examiner is impermissibly engaging in hindsight based on Applicants own disclosure that perilla oil is effective at treating cellulite. Reconsideration and withdrawal of this rejection is requested.

Having distinguished the independent claim from the art of record, Applicant submit that the claims dependent therefrom are patentable for at least the same reason. However,

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[1] Applicants submit herewith an article, Hourihane et al., "Randomized, double blind, crossover challenge study of allergenicity of peanut oils in subjects allergic to peanuts," *BMJ*, Vol. 314, pp. 1084–8 (1997), which establishes that "crude peanut oil caused allergic reactions in 10% of allergic subjects studied and should continue to be avoided," whereas "[r]efined peanut oil did not pose a risk to any of the subjects." Accordingly, Applicants again traverse the Examiner's contention that all peanut oil is allergenic.

Applicants reserve the right to separately address the patentability of the dependent claims in the future, should that become necessary.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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